

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	10/033,101
Filing Date	10/19/2001
First Named Inventor	Robert E. Dudley
Art Unit	1617
Examiner Name	Jiang, S.
Attorney Docket Number	01917590

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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
SAD		5152997	10/06/92	Ebert, et al.	
		5231087	07/27/93	Thornfeldt	
		5256652	10/26/93	El Rashidy	
		5324521	06/28/94	Gertner, et al.	
		5326790	07/05/94	Thornfeldt	
		5332577	07/26/94	Gertner, et al.	
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		5362497	11/08/94	Yamada, et al.	
		5413794	05/09/95	Suzuki, et al.	
		5446070	08/29/95	Mantelle	
		5460820	10/24/95	Ebert, et al.	
		5610150	03/11/97	Labrie	
		5629021	05/13/97	Wright	
		5641504	06/24/97	Lee, et al.	
		5643899	07/01/97	Elias, et al.	
		5648350	07/15/97	DeLingnieres	
		5651973	07/29/97	Moo-Young, et al.	
		5654337	08/05/97	Roentsch, et al.	
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		5770606	06/23/98	El Rashidy, et al.	
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		5788983	08/04/98	Chien, et al.	
		5807849	09/15/98	Labrie	
		5807957	09/15/98	Samour, et al.	
		5837289	11/17/98	Grasela, et al.	
		5847128	12/08/98	Martin, et al.	
		5855905	01/05/99	Oettel, et al.	
		5874074	02/23/99	Smith	
		5908619	06/01/99	Scholz	

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SAD		5908638	06/01/99	Huber, et al.	
		5932227	08/03/99	Higo, et al.	
		5955455	09/21/99	Labrie	
		5968919	10/19/99	Samour, et al.	
		6010716	01/04/00	Saunal, et al.	
		6019997	02/01/00	Scholz, et al.	
		6037346	03/14/00	Doherty, Jr., et al.	
		6075028	06/13/00	Graham	
		6077841	06/20/00	Sui, et al.	
		6087368	07/11/00	Macor, et al.	
		6117446	09/12/00	Place	
		6127363	10/03/00	Doherty, et al.	
		6156753	12/05/00	Doherty, et al.	
		6238284	05/29/01	Dittgen, et al.	
		6299900	10/09/01	Reed, et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
SAD		DE 3238984	10/21/82	Besins		
		EPO 0197753	10/15/96	Keenan, et al.		
		EPO 0581587 A2	02/02/94	Kobayashi, et al.		
		EPO 0804926	04/19/97	Jenapharm GMBH		
		FR 2515041	04/29/83	Besins		
		FR 2518879	07/01/83	Besins		
		FR 2519252	07/08/83	Besins		
		FR 2705572	02/12/94	Besins		
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		WO 0024362	05/04/00	Univ. Virginia Commonwealth		
		WO 0066870 A1	08/10/00	Lulla, et al.		
		WO 0076522 A1	12/21/00	Watson Pharm. Inc.		
		WO 0143775 A1	06/21/01	Luo, et al.		
		WO 9325168 A1	12/23/93	Heiber, et al.		
		WO 9325168 A1	12/23/93	Theratch Inc.		
		WO 9408590	04/28/94	BTG Pharm. Corp.		

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<i>SEA</i>		WO 9421230	09/28/94	Cellegy Pharm Inc		
		WO 9421271	09/29/94	Cellegy Pharm Inc		
		WO 9627372 A1	09/12/96	Int'l Medical		
		WO 9636339	11/21/96	Beth Israel Hosp		
		WO 9743989	11/27/97	Diversified Pharm Inc		
		WO 9808547	03/05/98	Seikisui Chemical Co Ltd		
		WO 9824451	06/11/98	Bio Technology General Corp		
		WO 9834621 A1	08/13/98	Rako		
		WO 9837871	09/03/98	Minnesota Mining & Mfg		
		WO 9924041 A1	05/20/99	Cellegy		
		WO 9932107	07/01/99	West Pharm Serv Drug Res Ltd		
<i>SEA</i>		WO 9966870 A1	12/29/99	Fotinos		

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NON PATENT LITERATURE

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- ABITBOL, et al., *Sex Hormones and the Female Voice*, J VOICE, 1999 Sep; 13(3): 424-46.
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BHASIN, *Clinical Review 34, Androgen Treatment of Hypogonadal Men*, JOURNAL OF CLINICAL Endocrinology and Metabolism, Vol. 74, No. 6, pp. 1221-1225 (1992).BHASIN, et al., *A Biodegradable Testosterone Microcapsule Formulation Providing Uniform Eugonadal Levels of Testosterone for 10-11 Weeks in Hypogonadal Men*, J CLIN ENDOCRINOL METAB, 1992 Jan; 74(1): 75-83.BHASIN, et al., *Therapeutic Perspective, Issues in Testosterone Replacement in Older Men*, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 83, No. 10, pp. 3435-3448 (1998)BISSCHOP, et al., *Effects of Nandrolone Decanoate on Respiratory and Peripheral Muscles in Male and Female Rats*, www.uth.tms.edu. (1996, Downloaded 10/8/98).BLOCH, et al. *Pituitary-Adrenal Hormones and Testosterone Across the Menstrual Cycle in Women with Premenstrual Syndrome and Controls*, BIOL PSYCHIATRY, 1998 Jun 15; 43(12): 897-903.BOCCHINFUSO, et al., *Expression and Differential Glycosylation of Human Sex Hormone-Binding Globulin by Mammalian Cell Lines*, MOL ENDOCRINOL, 1991 Nov; 5(11): 1723-1729.BONNEY, *Hormone Replacement Therapy for Men*, AMERICAN CLINICAL LABORATORY, November/December 1997, <http://iscpubs.com/pubs/acl/acl1197.html>BOOJI, et al., *Androgens as Adjuvant Treatment in Postmenopausal Female Patients with Rheumatoid Arthritis*, ANN RHEUM DIS, 1996 Nov; 55(11): 811-5.BOOTS, et al., *Measurement of Total Serum Testosterone Levels Using Commercially Available Kits: High Degree of Between-Kit Variability*, FERTIL STERIL, 1988 Feb; 69(2): 286-292.BOYLE, et al., *Serum Testosterone Measurements*, AM J CLIN PATHOL, 1984 Jun; 81(6): 754,761.BROCKS, et al., *Pharmacokinetics of Testosterone in Hypogonadal Men After Transdermal Delivery: Influence of Dose*, J CLIN PHARMACOL 1996; 36:732-739.BRUUN, et al., *Dihydrotestosterone Measured in Core Biopsies from Prostatic Tissues*, AM J CLIN ONCOL, 1988; 11 Suppl 2:S27-9.BUCKLER, et al. *The Effects of Low-Dose Testosterone Treatment on Lipid Metabolism, Clotting Factors and Ultrasonographic Ovarian Morphology in Women*, CLINICAL ENDOCRINOLOGY (1997) 49, 173-178.BUCKLER, et al., *Which Androgen Replacement Therapy for Women?*, J CLIN ENDOCRINOL METAB, 1998 Nov; 83(11):3920-4.BURGER, et al., *Effect of Combined Implants of Oestradiol and Testosterone on in Postmenopausal Women*, BR MED J (CLIN RES ED), 1987 Apr 11; 294(6577): 936-7.BURGER, et al., *The Management of Persistent Menopausal Symptoms with Oestradiol-Testosterone Implants: Clinical, Lipid and Hormonal Results*, MATURITAS, 1984 Dec; 6(4): 351-8.CAREY, et al., *Transdermal Testosterone Treatment of Hypogonadal Men*, THE JOURNAL OF UROLOGY, Vol. 140, pp. 76-79, (July 1988).CARLSTROM, et al., *Relationship Between Serum Testosterone and Sex Hormone-Binding Globulin in Adult Men with Intact or Absent Gonadal Function*, INTERNATIONAL JOURNAL OF ANDROLOGY, 1990, 13, pp. 67-73.CASHDAN, *Hormones, Sex and Status in Women*, HORMONES AND BEHAVIOR, 29, 354-366 (1995).Date
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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/033,101
		Filing Date	10/19/2001
		First Named Inventor	Robert E. Dudley
		Art Unit	1617
		Examiner Name	Jiang, S.
		Attorney Docket Number	01917590
Sheet 1 of 19	TECH CENTER 1600/2901		
NON PATENT LITERATURE			
Examiner Initials	No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
SEP		CASSON, et al., <i>Androgen Replacement Therapy in Women: Myths and Realities</i> , INT J FERTIL MENOPAUSAL STUD; 1996 Jul-Aug; 41(4):412-22.	
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		Attorney Docket Number	01917590
Sheet 6	of 19	TECH CENTER 1600/2900	

NON PATENT LITERATURE		
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		First Named Inventor	Robert E. Dudley	
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Sheet	of	19	Attorney Docket Number	01917590

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NON PATENT LITERATURE	
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SAD	GOOREN, A <i>Ten-Year Safety Study of the Oral Androgen Testosterone Undecanoate</i> , 1994 May-Jun; 15(3):212-5.
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	ISAACS, <i>Etiology of Benign Prostatic Hyperplasia</i> , EUR UROL, 1994; 25 Suppl 1:6-9.
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	JARKANDER-ROLFF, et al., <i>Transdermal Application of A Testosterone Gel – A Pharmacokinetic Study</i> .
SAD	JAVANBAKHT, et al., <i>Pharmacokinetics of a Novel Testosterone Matrix Transdermal System in Healthy, Premenopausal Women and Women Infected with the Human Immunodeficiency Virus</i> , J CLIN ENDOCRINOL METAB, 2000 Jul; 85(7): 2395-401.

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- JOCKENHOVEL, et al., *Pharmacokinetics and Pharmacodynamics of Subcutaneous Testosterone Implants in Hypogonadal Men*, CLINICAL ENDOCRINOLOGY, (1996) 45 61-71.
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Examiner Name	Jiang, S.
Attorney Docket Number	01917590

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NON PATENT LITERATURE

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Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

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NON PATENT LITERATURE	
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SAO	MAZER, et al., <i>Enhanced Transdermal Delivery of Testosterone: A New Physiological Approach for Androgen Replacement in Hypogonadal Men</i> , JOURNAL OF CONTROLLED RELEASE, 19 (1992) 347-362.
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SAO		RAKO, <i>Testosterone Deficiency: a Key Factor in the Increased Cardiovascular Risk to Women Following Hysterectomy or with Natural Aging?</i> J WOMENS HEALTH, 1998 Sep; 7(7): 825-9.
SAO		RINGHAM, et al., <i>Dose Proportionality and Systemic Bioavailability of a Testosterone Topical Gel In Hypogonadal Men</i> , Unimed Pharmaceuticals (October 31, 2000).
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First Named Inventor	Robert E. Dudley
Art Unit	1617
Examiner Name	Jiang, S.
Attorney Docket Number	01917590

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Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		"Sepa Testosterone Transdermal Gel Receives Application by FDA", DOCTOR'S GUIDE GLOBAL EDITION, http://pslgroup.com/dg/123aa.htm .
SPD		"Sex, Hormones, and Hysterectomies", THE NEW ENGLAND JOURNAL OF MEDICINE, Sept. 7, 2000, Vol. 343, No. 10, 730-731.
SPD		"Sexual Dysfunction in the Male, Sexual Arousal Disorder", THE MERCK MANUAL, Sixteenth Edition, Ch. 139, pp. 1575-1576 (1992).
		"SmithKline Beecham's New 5 mg Androderm Testosterone Transdermal System Now Available, INTERNATIONAL Association of Physicians in AIDS Care", http://www.iapac.org/clinmgmt/compnews/sb061297.html .
		"Testocreme - No Shots, No Pills, No Patches", www.testocreme.com (Downloaded 7/10/00).
SPD		"Testosterone 'Aids Post-Menopausal Women', BBC News Online: Health", www.bbc.co.uk . (June 14, 1999).
SPD		"Testosterone Gel May Help Men with Low Sex Drive", THE MEDICAL LETTER ON DRUGS AND THERAPEUTICS, Vol. 42 (Issue 1080), pp. 49-52 (June 12, 2000).
		"Testosterone Gel May Help Men with Low Sex Drive", WRAL ONLINE, http://www.wral-tv.com/features/healthteam/1997/0814-tgel/ .
		"Testosterone Patch Increases Women's Sex Drive," http://abcnews.go.com/sections/living/DailyNews/testosterone990615.html .
SPD		"Testosterone Therapy - for Women?", Health News, www.onhealth.com (May 7, 1996).
SPD		"Testosterone's Role in the Female Sex Drive", USA Today News, www.usatoday.com (April 8, 1996).
		"Testosterone", Chapters 1-16 (1999)
		"Testosterone", PREVENTIVE MEDICINE CLINIC OF MONTEREY, http://www.wellnessmd.com/testo.html .
		"The Testosterone Source", http://www.testosteronesource.com
		"Trials for the Treatment of Wasting", AIDS Treatment Data Network, www.aidsinfonyc.org (Downloaded 10/8/98).
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		"USP Drug Information - Anabolic Steroids (Systemic)", MayoClinic, www.mayohealth.org (Downloaded 10/8/98).
SPD		"Women and HIV", Women and HIV Discussion Paper, pp. 1-12 (1/98).

Date Considered

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/033,101
				Filing Date	October 19, 2001
				First Named Inventor	Robert E. DUDLEY
				Art Unit	1617
Examiner Name	S. JIANG				
Sheet	1	of	1	Attorney Docket Number	01917590

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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
SJD	1	4,663,157	05-05-87	Brock, E.D.	
	2	4,699,779	10-13-87	Palinczar, V.	
	3	5,023,252	06-11-91	Hsieh, D.	
	4	5,446,025	08-29-95	Lu, M.F.	
	5	5,731,303	03-24-98	Hsieh, D.	
	6	5,891,462	04-06-99	Carrara, D.	
	7	6,503,894	01-07-03	Dudley, R.E.	

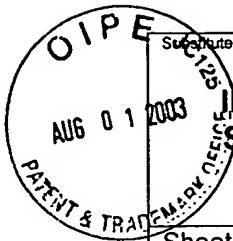
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
SJD	8	AU 4998490	09-20-90	Amway Corp.		
	9	AU 9141391	06-25-92	Theratech Inc.		
	10	EP 189861	08-06-86	Showa Denko		
	11	EP 332147	09-13-89	Warner-Lambert		
	12	EP 552405	11-25-98	Lintec Corp.		
	13	EP 811381	05-02-03	Permotech N.V.		
	14	GB 1158283	07-16-69	Foster-Milburn		
	15	JP 62-011675	08-02-94	TEZUKA		
	16	WO 87/03473	06-18-87	Hsieh, D.		
	17	WO 92/07586	05-14-92	Beecham Group PLC		

Examiner Signature	<i>SJD</i>	Date Considered	10/8/03
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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Sheet 1 of 1

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Filing Date	October 19, 2001
First Named Inventor	Robert E. DUDLEY
Art Unit	1617
Examiner Name	S. JIANG
Attorney Docket Number	01917590

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SJD	1	DELANOE et al., "Androgenisation of Female Partners of Men on Medroxyprogesterone Acetate/Percutaneous Testosterone Contraception," The Lancet (Feb 1984), p. 276.	
	2	DEMERY, A. "Contraception Masculine" Soins Gyn.-Obs.-Puer.-Ped., No. 72 (May 1987) pp. 33-38.	
	3	MARBURY et al., "Evaluation of the Pharmacokinetic Profiles of the New Testosterone Topical Gel Formulation, Testim(TM), Compared to AndroGel(R)," Biopharm. Drug Dispos., 24:115-120 (2003).	
	4	MORGAN et al., "Enhanced Skin Permeation of Sex Hormones with Novel Topical Spray Vehicles," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1213-1218.	
	5	MORGAN et al., "Enhanced Transdermal Delivery of Sex Hormones in Swine with a Novel Topical Aerosol," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1219-1225.	
	6	POPE JR., et al., "Testosterone Gel Supplementation for Men with Refractory Depression: A Randomized, Placebo-Controlled Trial," Am. J. Psychiatry, 160(1): 105-111 (2003).	
	7	SCHOOR, M., "Livening Up Libidos: Testosterone Patches Can Help Revive Women's Sex Drive," www.abcnews.com, September 6, 2000.	
	8	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1998, filed on March 22, 1999.	
	9	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1999, filed on March 14, 2000.	
	10	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1996, filed on March 28, 1997.	
	11	CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1997, filed on March 31, 1998.	
	12	CELLEGY PHARMACEUTICALS, INC.: INVESTORS: PRESS RELEASES, "Cellegy Pharmaceuticals Receives FDA Nonapproval Letter for Fortigel," July 7, 2003, www.cellegy.com.	
	13	PERCUTACRINE STRONG ANDROGENIC Testosterone Percutacrine Androgenique Forte from VIDAL dictionary (1985).	X
	14	Protest Under 37 CFR 1.291(a) of U.S. Patent Application No. 09/651,777 dated August 20, 2002.	

Examiner Signature		Date Considered	10/8/03
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